K071718

Summary of Safety and Effectiveness

JUL 13 2007

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen McKelvey, MA, RAC Senior Manager, Corporate Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	June 20, 2007
Trade Name:	*Trilogy*® *Longevity*® Constrained Liner
Common Name:	Constrained Acetabular Liner
Classification Names and References:	21 CFR 888.3310: Hip joint metal / polymer constrained cemented or uncemented prosthesis, Product code: KWZ
Predicate Device:	Zimmer (formerly Centerpulse) *Epsilon*™ *Durasul*® Constrained Acetabular Liner, K030923, cleared October 3, 2003
Device Description:	The *Trilogy Longevity* Constrained Liner is a polyethylene/metal acetabular liner, which, when used with a *Trilogy* or *Trabecular Metal* ™ Modular Acetabular Shell, forms the acetabular component of a total hip prosthesis. The device consists of a *Longevity* Highly Crosslinked Polyethylene Liner and a *Tivanium*® alloy constraining ring. The liner allows for mechanical capture of the metal femoral head and greater flexion/extension range of motion than hooded constrained liner designs.
Intended Use:	The *Trilogy Longevity* Constrained Liner is indicated for primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition.

	This device is intended for patients for whom all other options to constrained acetabular components have been considered.
Comparison to Predicate Device:	The *Trilogy Longevity* Constrained Liner is a design modification of the *Epsilon Durasul* Constrained Acetabular Liner. The material has been changed to *Longevity* Highly Crosslinked Polyethylene, the finger and ring designs have been modified to ease assembly and the backside has been modified for use with *Trilogy* and *Trabecular Metal* Modular Acetabular Shells.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Mechanical testing of the modified device indicates that it is substantially equivalent to the predicate. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Zimmer, Inc.
% Mr. Stephen McKelvey, MA, RAC
Senior Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K071718
Trade/Device Name: *Trilogy® Longevity®* Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: June 20, 2007
Received: June 22, 2007

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071718

Device Name:

Trilogy® *Longevity*® Constrained Liner

Indications for Use:

The *Trilogy*® *Longevity*® Constrained Liner is indicated for primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071718